



Practitioner's Docket No. U 014689-8

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

**OR**

In re application of: Manne Satyanarayana **REDDY**, et al.

Serial No.: 10/601,844

Group No.: 1614

Filed: June 23, 2003

Examiner:

For: AMORPHOUS FORM OF (-)-[2-[4-[(4- CHLOROPHENYL)-PHENYLMETHYL]-1-PIPERAZINYL]ETHOXY] ACETIC ACID DIHYDROCHLORIDE  
(LEVOCETIRIZINE DIHYDROCHLORIDE)

**Commissioner for Patents**

**P. O. Box 1450**

**Alexandria, VA 22313-1450**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))**

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

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Date: October 17, 2003

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JANET I. CORD

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\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: 37 C.F.R. 1.98(b):

- (1) *Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.*
- (2) *Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.*
- (3) *Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.*
- (4) *Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.*
- (5) *Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.*

**WARNING:** *No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).*

NOTE: *The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).*

## **IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

NOTE: *"No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."*

NOTE: *"An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

NOTE: *"The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

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**SIGNATURE OF PRACTITIONER**

JANET I. CORD

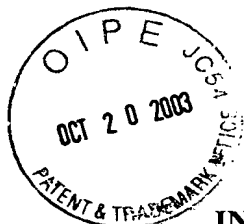
(type or print name of practitioner)

LADAS & PARRY

P.O. Address

26 WEST 61<sup>ST</sup> STREET

NEW YORK, N.Y. 10023



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Manne Satyanarayana **REDDY**, et al.

Serial No.: 10/601,844

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Filed: June 23, 2003

Examiner:

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(LEVOCETIRIZINE DIHYDROCHLORIDE)

Attorney Docket No.: U 014689-8

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

We draw the attention of the Examiner to the attached English-language version of an International-type Search Report from a foreign office in respect of counterpart International Application No. PCT/US 03/19777 that indicates the degree of relevance found by the foreign

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**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

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Date: October 17, 2003

  
Signature

JANET I. CORD

(type or print name of person certifying)

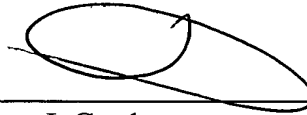
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"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

October 17, 2003

office. The Search Report makes consideration of any non-English art required. MPEP 609.

Form PTO-1449 is also attached with reference copies.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Janet I. Cord", is written over a horizontal line.

Janet I. Cord  
Ladas & Parry  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023  
Reg. No.: 33,778 (212) 708-1935

FORM PTO-1449

U. S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

U 014689-8

10/601,844

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT

Manne Satyanarayana REDDY, et al.

FILING DATE

GROUP

June 23, 2003

1614

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
	AA				
	AB				
	AC				
	AD				
	AE				
	AF				
	AG				
	AH				
	AI				
	AJ				
	AK				

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL					
	AM					
	AN					
	AO					
	AP					

## OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

AR	Tang, X., et al. "Enantiomeric Separation of Cetirizine Hydrochloride by HPLC." CHEMICAL ABSTRACT SERVICE, database accession no. 139:74203, XP002255199 (2002) 22 (4) pp 311-312
AS	Pflum, D.A., et al. "A Large-Scale Synthesis of Enantiomerically Pure Cetirizine Dihydrochloride Using Preparative Chiral HPLC" <i>Organic Process Research &amp; Development</i> (2001) 5(2) pp 110-115
AT	Gillard, M., et al. "Binding Characteristics of Cetirizine and Levocetirizine to Human H1 Histamine Receptors: Contribution of Lys191 and Thr194" <i>Molecular Pharmacology</i> (2002) 61(2), pp 391-399

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.